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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,129	08/22/2003	Todd Bucciarelli	MBHB04-101-C	8860

7590 01/24/2007
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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/646,129

Applicant(s)

BUCCIARELLI ET AL.

Examiner

Michail A. Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 and 63 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 and 43-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-42, 57-60 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/30/06 has been entered.

Claims 1-60 and 63 are pending.

Claims 1-30 and 43-56 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 31-42 and 57-60 and 63, drawn to an expression vector comprising a minimal promoter comprising TATA sequence and two phase tetracycline operators downstream from TATA sequence and two phased tetracycline operators downstream from TATA sequence are under consideration in the instant application.

2. Claim 31 is objected to because of the following informalities: the word "TATA" is misspelled in line 7 of said claim.

Appropriate correction is required.

In view of the amendment, filed 11/30/06 the following rejections remain:

3. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 31-42 and 57-60 and 63 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 31-42 and 57-62 are indefinite and ambiguous in the recitation of "at least two tetracycline operator elements, wherein a first and a second phased tetracycline operator are downstream from TATA sequence and third and fourth phase tetracycline operator are upstream

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from the TATA sequence”. It appears that the vector claimed in claim 31 **should have at least four** tetracycline operator elements (the first and the second downstream from TATA and third and fourth phase tetracycline operator upstream from the TATA sequence) , not two as recited in the amended claim 31.

6. Claim 32 and 34 are indefinite and ambiguous in the recitation of “two phases tetracycline operators downstream from the TATA sequence are 21 basepairs downstream from the TATA sequence”. If the claimed expression vector comprises **two** tetracycline operators that both located downstream from the TATA sequence, then it is unclear how each of the two operators can be located 21 basepairs downstream from the TATA sequence ?

7. Claim 33 and 34 are indefinite and ambiguous in the recitation of “ two phases tetracycline operators upstream from the TATA sequence are 11 basepairs upstream from the TATA sequence ”. If the claimed expression vector comprises **two** tetracycline operators that both located upstream from the TATA sequence, then it is unclear how each of the two operators can be located 11 basepairs upstream from the TATA sequence ?

8. Claim 42 is indefinite and ambiguous in the recitation of “ wherein the vector encodes more than one cyclin-dependent kinase inhibitor”. The base claim 39 recites a vector comprising a **gene** that encodes a **cyclin dependent kinase inhibitor**. In other words, the claimed vector encoded only one cyclin-dependent kinase inhibitor. It is unclear how said vector, comprising only one specific gene can encode more than one cyclin-dependent kinase inhibitors?

9. Claim 59 is indefinite and ambiguous in the recitation of “ the expression vector of claims 57 or 58, wherein the peptide comprising said multiplicity of Cy motifs”. There is insufficient antecedent basis for this limitation in the claims, since base Claims 57 and 58 do not recite “peptide”.

10. Claims 57, 58 , 60 and 63 are indefinite and ambiguous in the recitation of “Cy motifs”. The characteristics and metes and bounds of “Cy motifs ” are unclear and indefinite, not defined by the claim and the specification does not provide a standard for ascertaining what Applicant means by “Cy motifs”.

11. Also an issue is that claims 60 and 63 are indefinite and ambiguous in the recitation of “ Cy motifs having the same or different amino acid sequence”. It is unclear what Applicant means by said phrase, since there is no clear recitation of specific amino acid sequences of Cy motifs in claims 57 and 58.

Applicant’s arguments, filed 11/30/06 have been fully considered, but have not been found convincing.

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Applicant asserts that : (i) amended claim 32 33 and 34 now recites the distances related to the position of the TATA sequence in the expression vector. (iii) indefinite article “a” denotes “at least one” and not limited with regards to the number.

Contrary to Applicant's assertion, the amended claims 32, 33 and 34 still recites the expression vector, wherein **two** tetracycline operators, i.e. the first and the second both located 21 basepairs downstream from the TATA sequence and the third and fourth are both located 11 basepairs upstream from the TATA sequence . If the first phased tetracycline operator located 21 basepairs downstream from the position of the TATA sequence, then how can the second phased tetracycline operator been located at the same position ? Similarly, if the third operator is located 11 basepairs upstream from the position of TATA sequence , than how can the fourth operator been located at the same position?

With regards to the claim 42.

Contrary to Applicant's assertion the indefinite article “a” does not denote “more than one”, but rather that only one of the specific cyclin dependent kinase inhibitor, recited in claim 41 is encoded. Applicant attention is respectively directed to claim 40, wherein it is explicitly recited that the gene encodes **a cyclin dependent kinase inhibitor** (emphasis added). It is the Examiner position that the word “inhibitor” in said claim means single not plural number. Thus, it is unclear how a vector, comprising only a gene that encode only one cyclin dependent kinase inhibitor can encode **more than one** cyclin-dependent kinase inhibitors?

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13 . Claims 57-60 and 63 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

“ The expression vector of claim 31, wherein the expression vector encodes one or a multiplicity of Cy motifs, wherein the Cy motifs encode a peptide having an amino acid sequence identified by SEQ ID Nos:3,4,5,6,7,8,9,10,11,12,or 13 ” claimed in claims 57-60 and 63 represent(s) a departure from the specification and the claims as originally filed. The specification and the claims as originally filed only support “The expression vector of claim 31, wherein the expression vector encodes cyclin-dependent kinase inhibitors selected from the group recited in claims 41 and 42.

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Applicant's arguments, filed 11/30/06 have been fully considered, but have not been found convincing.

Applicant asserts that disclosure of the Specification on pages 19 -20 and in Table I fully supports claims 57-60 and 63.

Contrary to Applicants assertion, it is noted that specification on pages 19 and 20 only generally disclosed that peptides that may be used include Cy regions peptide. Moreover, page 19 of the Specification only provide a general disclosure that multimeric repeats of Cy motifs controlled by an inducible system are used to provide multiple Cy inhibitory species. Table I only disclosed several known peptides that have Cy motif in their sequences.

It is the Examiner position that the generic disclosure on page 19 and table I of the Specification does not support the specific recitation of " The expression vector of claim 31, wherein the expression vector encodes one or a multiplicity of Cy motifs, wherein the Cy motifs encode a peptide having an amino acid sequence identified by SEQ ID Nos: 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, or 13 " claimed in claims 57-60 and 63. In re Ruschig, 154 USPQ 118---- Where a species of a properly described genus was found not to be described. A generic or a sub-generic disclosure cannot support a species unless the species is specifically described.

14. No claim is allowed

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAIL BELYAVSKIY, PH.D.
PATENT EXAMINER

1/17/07